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DEC 2 1 2004

510(k) Summary

Submitted by:

Keith Paluch
Consultant
Churchill Medical Systems
87 Venture Drive
Dover, NH 03820

Proposed Device:

Dual Chamber Empty Container

Product Classification:

Class II C.F.R. 880.5025 Product code: KPE

FDA registration number:

1223004

Predicate Devices:

510(k)	Name	Manufacturer
K960581	Dual Chamber Empty Container	Secure Medical Products
K911567	Dual Chamber Empty Container	Stedim Inc.
K020485	Two Chamber Container	Baxter Healthcare Corp.
K972464	Vitamix Container[1]	Pacific Device

Device Description:

The Churchill Medical Systems Dual Chamber Empty Container is a sterile non-invasive fluid container used for compounding, storage and administration of total parenteral nutrition (TPN) solutions. This device is a sterile, single use disposable I.V. container that is horizontally divided into two chambers. The top chamber is intended for the storage of amino acid/ dextrose mixtures. The bottom chamber is intended to store lipid emulsions. Additive medication may

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be introduced into the bottom compartment by access through a non-latex injection port. The chambers are designed to be filled with TPN solution by a pharmacy operation.

The filled container is intended to be stored with the divider/seal intact until the time of administration to the patient.

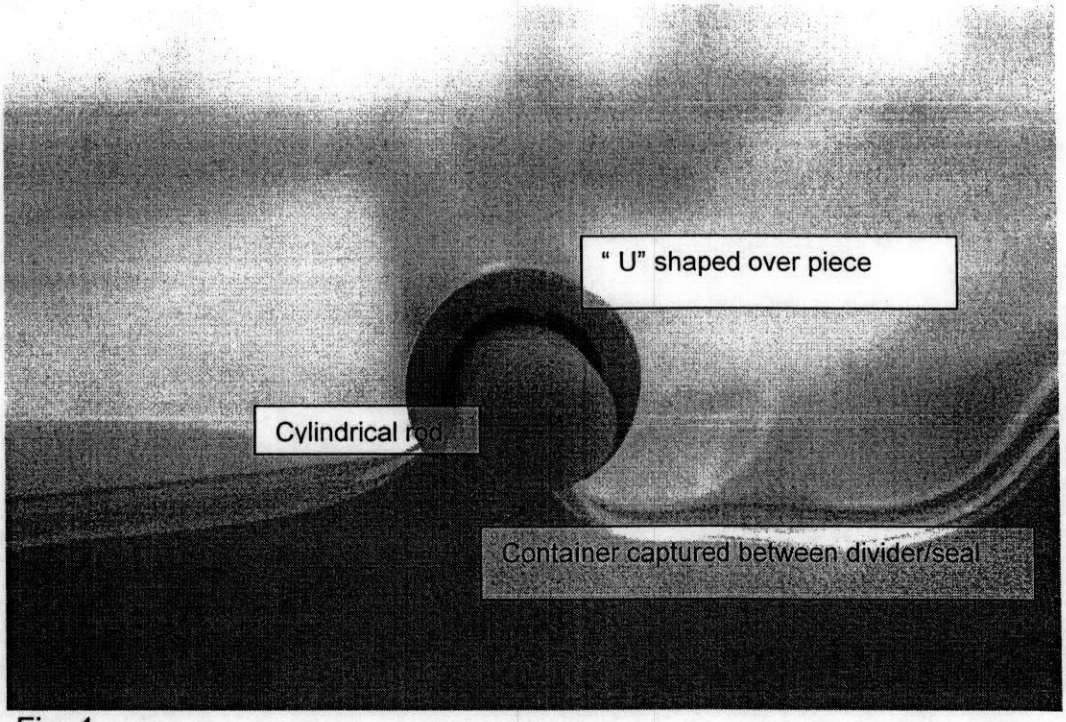


Fig. 1

At the time of patient use the divider/seal (Fig 1) is removed by peeling the external seal that separates the container top chamber from bottom chamber. The combined fluids are and then dispensed to the patient through a secondary set not included with this device.

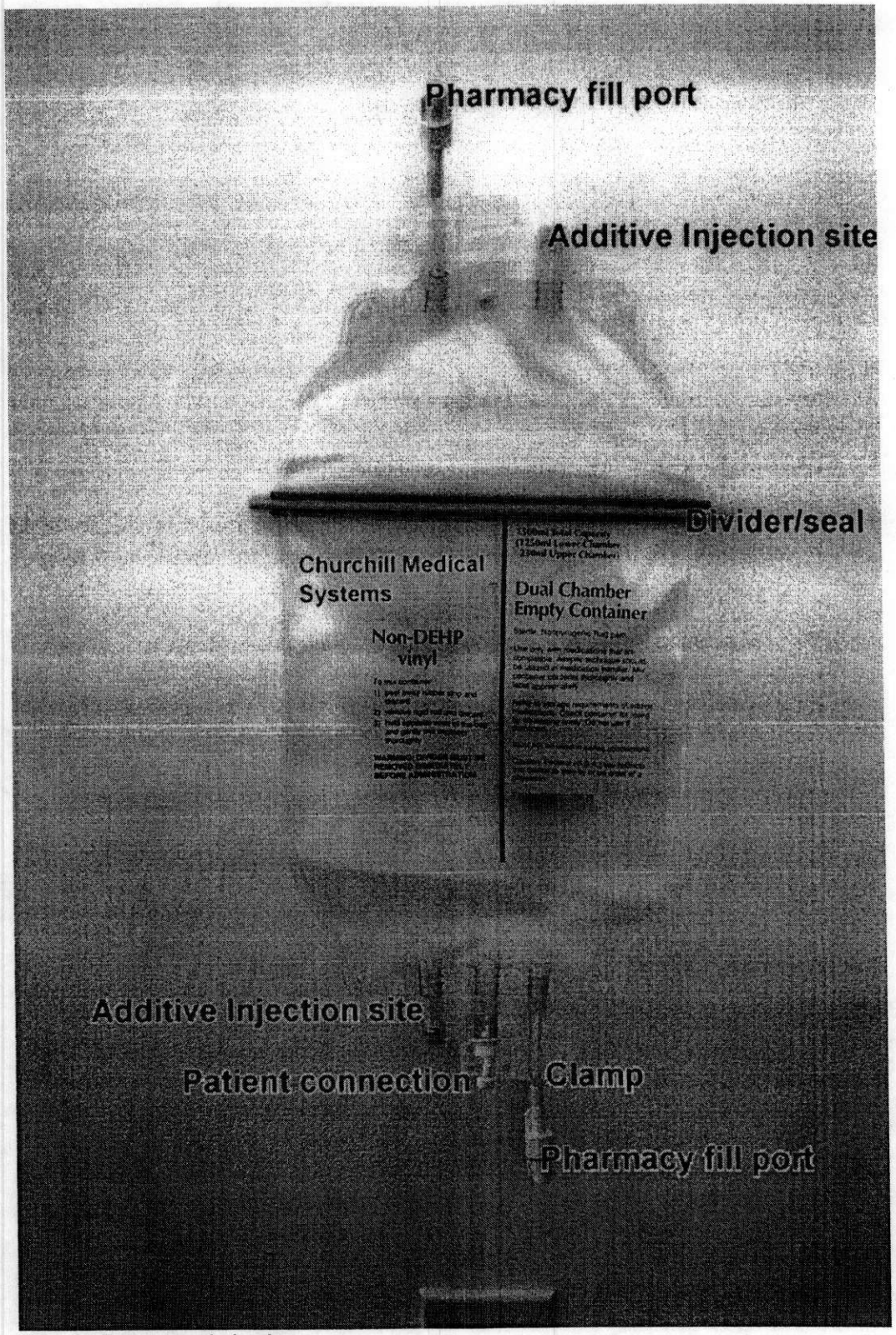


Fig. 2 Proposed device

Information On the Device Specifications:

The container is made from extruded stock non-DEHP vinyl.
Each chamber is provided with a Pharmacy filling port, filling port clamp, non-latex injection site, and one patient delivery port located at the device bottom.

All materials used and manufacturing processes are identical to the original submission K972464. The divider/seal is a two-piece component that consists of a center cylindrical rod and a tightly fitting "U" shaped over piece. The container is bag like and separated when the divider is placed over the exterior bag surface. The divider/seal does not contact any fluid or medication but, works to occlude the two chambers from one another by forming a compression seal when the bag is squeezed between.

The container must not leak either internally or externally when filled with fluid and subjected to a compressive force of 20 pounds for a minimum of 10 minutes.

The container must mix freely when the divider/seal is removed.

The device is ETO sterilized. ETO residuals specified as less than 2mg (AAMI TIR 19) *ETO residual ECH is less than 25ppm. EG is less than 500ppm.*[2]

Non- pyrogenic fluid path way.

Comparison to predicate device:

Similarities[3]

Proposed and all predicate devices have the same indications for use.
Proposed and predicate devices are manufactured from non-DEHP vinyl extruded roll stock.
All devices use familiar and interchangeable pharmacy connectors and needle access injection sites.
Proposed and predicate device are ETO sterilized.
Proposed and predicate devices are 1500 ml in total volume.
Proposed and predicate have similar divider/seal and are manufactured in HDPE and Kraton rubber.
Instructions for use are similar.
Proposed and predicate devices are sterile and non-pyrogenic.

Differences[4]: K972464 is a single chamber device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Mr. Keith Paluch
Consultant
Churchill Medical Systems, Incorporated
87 Venture Drive
Enterprise Park
Dover, New Hampshire 03820

Re: K041038
Trade/Device Name: Churchill Medical Dual Chamber Empty Container
Regulation Number: 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: November 24, 2004
Received: December 8, 2004

Dear Mr. Paluch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

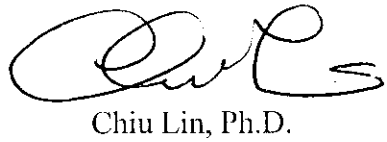
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): KO41038

Device Name: Churchill Medical Dual Chamber Empty Container

Indications For Use: Churchill Medical Dual Chamber Empty Container is intended for the compounding, storage, and administration of total parenteral nutrition (TPN) solutions.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041438